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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,711	04/20/2001	Darwin J. Prockop	53844-5005	6580
7590 10/06/2003				
KATHRYN DOYLE, PH.D., J.D. MORGAN, LEWIS & BOCKIUS, L.L.P. 1701 Market Street Philadelphia, PA 19103-2921			EXAMINER KELLY, ROBERT M	
			ART UNIT 1632	PAPER NUMBER

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/839,711	Applicant(s) PROCKOP ET AL.	
	Examiner Robert M Kelly	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the Applicants for patent have not signed the declaration.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of Claims 1, 5, 9, and 13-16 comprise administering stromal cells "from an allogenic but otherwise identical donor." This statement is indefinite as it is unknown what else is "otherwise identical" between the recipient and the donor. However, for purposes of compact prosecution, the term "allogenic but otherwise identical donor" will be interpreted as "allogenic donor" in each of the claims. Please correct this indefinite phrase.

Claims 2-4, 6-8, and 10-12 are rejected for depending upon an indefinite base Claims 1, 5, and 9, respectively.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-6, 8-10, and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Anklesaria, et al. "Engraftment of a clonal bone marrow stromal cell line *in vivo* stimulates hematopoietic recovery from total body irradiation" (1987) Proc. Natl. Acad. Sci., USA, 84: 7681-85, hereinafter referred as "Anklesaria '87".

Claims 1, 5, 9, and 13-16 encompass methods of rescuing (Claim 1) or treating (Claim 14) of a mammal, or increasing hematopoiesis in a mammal (Claims 5, 9, 13 and 15), or increasing the survival of a mammal (Claim 16), wherein the method comprises administering marrow stromal cells from an allogenic animal. The mammal being rescued or treated having been exposed to radiation (Claims 1, 9, 13, and 16), or has for some reason, damaged bone marrow (Claims 14-15). Whether the mice have damaged marrow due to irradiation or another

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reason is considered irrelevant to the claims, as the method is concerned with recovery, not with a method of damaging the marrow. Claims 2, 6, and 10 narrow the mammal to, inter alia, a rodent. Claims 4, 8, and 12 limit the method of engraftment to infusion.

Ankelsaria '87 teaches engraftment of an allogenic stromal cell line via intravenous injection (infusion), of irradiated mice (a rodent) (ABSTRACT). Such mice demonstrated increased hematopoiesis and significantly enhanced hematopoietic recovery over control mice (ABSTRACT).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 7, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anklesaria '87 as applied to Claims 1-2, 5-6, and 9-10 above, and further in view of U.S. Patent No. 5,635,386 to Palsson, et al., hereinafter referred to as "Palsson '386".

Claims 3, 7, and 11 further limit 1-2, 5-6, and 9-10, respectively, to methods entailing humans.

As stated above, Claims 1-2, 5-6, and 9-10 are taught by Anklesaria '87, however Anklesaria '87 does not teach humans. On the other hand, Palsson '386 teaches the use of human hematopoietic stem cells and their cultures that "afford improved methods for bone marrow transplantation." Moreover, one of skill in the art at the time the invention was made

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would have been motivated to modify the teachings of Anklesaria '87 with that of Palsson '386, and use human cell lines in humans to obtain the benefit of rescuing humans exposed to radiation or enhance hematopoiesis. Furthermore, the artisan would have had a reasonable expectation of success, as bone marrow transplantation was already known and the cultures taught by Palsson '386 were known to afford improved methods for bone marrow transplantation, which necessarily demonstrates that cell lines themselves may be used in bone marrow transplantation in humans.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M Kelly whose telephone number is (703) 305-4460. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.


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